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EXAMINER

KRUSE, DAVID H

ART UNIT PAPER NUMBER

1638

DATE MAILED: 05/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/622,201

Applicant(s)

BARRY ET AL.

Examiner

David H. Kruse

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 2 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-131 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-131 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 18 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119.

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other

DETAILED ACTION

1. The patent sought to be reissued by this application is involved in litigation. Any documents and/or materials which would be material to the patentability of this reissue application are required to be made of record in reply to this action.

Due to the related litigation status of this application, **EXTENSIONS OF TIME UNDER THE PROVISIONS OF 37 CFR § 1.136(a) WILL NOT BE PERMITTED DURING THE PROSECUTION OF THIS APPLICATION.**

2. Applicant is reminded of the continuing obligation under 37 CFR § 1.178(b), to timely apprise the Office of any prior or concurrent proceeding in which Patent No. 5,633,435 is or was involved. These proceedings would include interferences, reissues, reexaminations, and litigation.

Applicant is further reminded of the continuing obligation under 37 CFR § 1.56, to timely apprise the Office of any information which is material to patentability of the claims under consideration in this reissue application.

These obligations rest with each individual associated with the filing and prosecution of this application for reissue. See also MPEP §§ 1404, 1442.01 and 1442.04.

Oath/Declaration

3. The reissue oath/declaration filed with this application is rejected under 35 U.S.C. § 151 (see 37 CFR § 1.175 and MPEP § 1414) because of the following: The error ~~statement in the Declaration filed 18 July 2003 is not deemed to be specific, nor does it~~ point out how the proposed error is corrected. Said declaration lacks a statement that

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the undersigned has reviewed the claims as amended as required under 37 CFR § 1.63(b)(2) and 37 CFR § 1.175(a). The Preliminary Amendment filed 7 March 2005 was not accompanied by a new Oath or Declaration, and the Declaration filed 18 July 2003 failed to state the error to which the second preliminary amendment is directed.

Appropriate correction is required.

Information Disclosure Statement

4. The information disclosure statement filed 11 April 2005 has been considered in part. References C41, C43, C44 and C48 have not been considered, and will not be published on the face of the reissue patent because they are in Japanese, and no translations have been provided. The Examiner acknowledges Applicant's summary interpretation of the references on pages 1-2 of the IDS.

Specification

5. The disclosure is objected to because of the following informalities: The amended Sequence Listing filed on 7 March 2005 fails to comply with 37 CFR § 1.173(b)(1) and (d)(2) because the introduced SEQ ID NO: 70 is not underlined to indicate insertion of new text. See MPEP § 1453.

6. The amendment to the Sequence Listing filed 7 March 2005 is objected to under 35 U.S.C. § 251 as being based upon new matter added to the patent for which reissue is sought. The added material, which is not supported by the prior patent, is as follows:

The amino acid sequence disclosed in SEQ ID NO: 70.

~~Applicant is required to cancel the new matter in the reply to this Office Action.~~

Priority

7. The claim of priority under 35 USC § 120 filed 18 July 2003 is noted, but said claim appears confusing because the instant application is being examined as a reissue, and not a divisional. This application is claiming the benefit of a prior filed nonprovisional application under 35 U.S.C. §§ 120, 121, or 365(c). Copendency between the current application and the prior application is required.

Claim Objections

8. Claims 2, 3, 5-14, 16-23, 24-31, 33-85, 88-105 and 113 are objected to because of the following informalities:

At claims 2 and 3, "A DNA molecule" should read -- The DNA molecule -- in referring to claim 1.

At claims 5-14, 41-68, 88-103 and 105, "A DNA molecule" should read -- The DNA molecule -- in referring to a previous claim.

At claims 16-23, "A method" should read -- The method -- in referring to a previous claim.

At claims 24, 74 and 104, "claims" should read -- claim --, because the list at line 2 is in the alternative. In addition "a DNA" should read -- the DNA -- in referring to a previous claim.

At claims 25-31, 69-73, and 75-78, "A glyphosate-tolerant" should read -- The glyphosate-tolerant -- in referring to a previous claim.

At claims 33-40, "A method" should read -- The method -- in referring to a previous claim.

At claims 79-85, "a glyphosate-tolerant" should read -- the glyphosate-tolerant -- in referring to a previous claim.

At claim 87, "a soybean" should read -- the soybean -- in referring to claim 86.

At claim 104, line 1, "claims" should read -- claim --, because the list at line 2 is in the alternative. In addition "a DNA" should read -- the DNA -- in referring to a previous claim.

Claim 113 is objected to because the limitation "producing...plants" at line 1 in the preamble is not in number agreement with the last step of the claimed method, which recites "a...plant".

Appropriate correction is required.

9. Claims 6, 8, 16, 19, 33, 36 and 88-105 are objected to under 37 CFR § 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The instant claims are dependent upon a base claim that recites that "provided that when X_1 is D, X_2 is T, X_3 is S, and X_4 is V, then X_5 is not P", while the instant claims encompasses that when X_1 is D, X_2 is T, X_3 is S, and X_4 is V, then X_5 can be P.

Claim Rejections - 35 USC § 251

10. Claims 1-131 are rejected as being based upon a defective reissue declaration under 35 U.S.C. § 251 as set forth above. See 37 CFR § 1.175.

The nature of the defect(s) in the declaration is set forth in the discussion above in this Office action.

Claim Rejections - 35 USC § 112

11. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

12. Claims 7, 9, 10, 14, 17, 20, 34, 79-85, 87-90 and 93 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 7, 9, 17, 20, 34, 88, 89, 90 and 93 are indefinite because the list of SEQ ID NOs further limits "an EPSPS enzyme" and not the "DNA sequence", said sequences being nucleic acid sequences and not amino acid sequences. Appropriate correction is required.

Claim 10 is indefinite because the limitation "the EPSPS sequence" lacks proper antecedent basis in the claim(s) upon which it depends.

Claims 79-85 and 87 are indefinite because it is unclear if the claimed seed, of a glyphosate-tolerant plant, comprises the transgene or if a non-transgenic seed is encompassed, hence the metes and bounds of the claims are unclear.

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 86 and 87 are rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably

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convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicant claims a transgenic soybean plant which contains a heterologous gene that encodes an EPSPS enzyme having an K_m for phosphoenolpyruvate (PEP) between 1 and 105 μM and a $K_m(\text{glyphosate})/K_m(\text{PEP})$ ratio between about 2 and 500.

Applicant does describe the structural features of such an EPSPS enzyme encoded by a heterologous gene as broadly claimed. Hence, it is unclear that Applicant was in possession of the invention as broadly claimed.

See *University of California V. Eli Lilly and Co.*, 43 USPQ2d 1398 (Fed. Cir. 1997), which teaches that the disclosure of a process for obtaining cDNA from a particular organism and the description of the encoded protein fail to provide an adequate written description of the actual cDNA from that organism which would encode the protein from that organism, despite the disclosure of a cDNA encoding that protein from another organism. At 1406, the court states that a description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. See also, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional

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characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

15. Claims 4, 5, 15, 18, 32, 35, 41-52 and 106-131 are rejected under 35 U.S.C. §§ 251 and 112, first paragraph, as being based upon new matter added to the patent for which reissue is sought. The added material, which is not supported by the prior patent, is as follows:

At claims 4, 5, 15, 18, 32, 35 and 41-52, the limitation "provided that when X_1 is D, X_2 is T, X_3 is S, and X_4 is V, then X_5 is not P" in claims 4, 15 and 32 introduces new matter into the claims. A review of the specifications does not provide any evidence that Applicant had contemplated this subgenus, and that again and again Applicant had stated that when X_1 is D, X_2 is T, X_3 is S, and X_4 is V, then X_5 could be P (see for example column 5, lines 5-20; column 26, line 45). Such a narrowing is viewed by the Examiner as introducing New Matter into the claims in view of *Purdue Pharma L.P. v. Faulding Inc.*, 56 USPQ2d 1481 (CA FC 2000). In *Purdue Pharma L.P.*, the court taught that in the case of the '360 patent, there was nothing in the written description that would suggest to one skilled in the art that the claimed ratio is an important defining quality of the formulation, nor did the disclosure motivate one to calculate the ratio (at 1486). In the instant application, Applicant's specification does not motivate one of skill in the art to exclude the inclusion of the specific amino acid proline from the EPSPS sequence and only look to those of the claimed subgenus.

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At claims 106-131, an isolated DNA molecule encoding and EPSPS enzyme having the sequence of SEQ ID NO: 70 introduces New Matter into the claims because there is no guidance in the specification that would lead one of skill in the art to such a species given Applicant's description of the invention. See the reasons given supra.

Conclusion

16. Due to the related litigation status of this application, EXTENSIONS OF TIME UNDER THE PROVISIONS OF 37 CFR § 1.136(a) WILL NOT BE PERMITTED DURING THE PROSECUTION OF THIS APPLICATION. A shortened statutory period to respond to this Office action is set at 2 months.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to David H. Kruse, Ph.D. whose telephone number is (571) 272-0799. The examiner can normally be reached on Monday to Friday from 8:00 a.m. to 4:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Amy Nelson can be reached at (571) 272-0804. The fax telephone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group Receptionist whose telephone number is (571) 272-0547.

DAVID H. KRUSE, PH.D.
PRIMARY EXAMINER



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18. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.